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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/779,767	01/07/1997	HABIB ZAGHOUANI	ALLIA.143A	6240

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EXAMINER	
NOLAN, PATRICK J	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 01/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
08/779,767	Zaghouani
Examiner	**Art Unit**
Patrick J. Nolan	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *Oct 1, 2001*

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4, 6, 9, 11, 24, 26, 27, 29, 66-70, and 72-74* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideratio

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4, 6, 9, 11, 24, 26, 27, 29, 66-70, and 72-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some* c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)

16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18)☐ Interview Summary (PTO-413) Paper No(s). _____

19)☐ Notice of Informal Patent Application (PTO-152)

20)☐ Other:

Part III DETAILED ACTION

1. Claims 4, 6, 9, 11, 24, 26-27, 29, 66-70 and 72-74 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:
A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 4, 6, 9, 11, 24, 26, 27, 29, 66-70 and 72-74 stand rejected under 35 U.S.C. § 103 as being unpatentable over Bona et al. (U) in view of Kuchroo et al. (U), all of record, for reasons stated in Paper Nos. 21, 26 and 35.

Applicant's arguments filed 10-01-01 have been fully considered but are not found persuasive.

Applicant's argue that in view of their amendment to the claims that said compositions prevent T cell activation and Figure 5 of the specification demonstrating said prevention and in view of the declaration submitted 4-3-00, demonstrating no recurrence of EAE for 120 days in mice treated with their composition, the claimed invention is non-obvious due to an unexpected result.

However, the unexpected result must be commensurate with the claimed invention. Applicant's claimed invention is drawn to using

any T cell receptor antagonist bound to an immunoglobulin portion wherein said portion binds a Fc receptor and is endocytosed by cells bearing said Fc receptor and wherein said composition processed by the cells to present said T cell receptor antagonist in association with MHC Class II molecules, thereby preventing T cell activation. The purported unexpected showing is one T cell receptor antagonist in an animal model of EAE. The scope of the claimed invention is significantly broader. In addition, the Examiner is require to determine whether or not the unexpected showing is unexpected in view of the totality of the references. Kuchroo et al., teaches the claimed PLP antagonist peptide and Bona et al., teaches the Ig construct and teachings for making an antagonist-Ig construct. Kuchroo et al, teaches similar concentrations of PLP peptide antagonist was effective in preventing T cell activation, see Table III. Kuchroo et al., teaches that 1nmol/ml concentration, equivalent to 1μM, was effective for a IC50 of T cell activation, while figure 5, teaches that .05μM concentration of Ig-PLP antagonist was effective at blocking T cell activation. So the construct was 20 times more effective that peptide alone in preventing T cell activation. However, Bona et al, specifically teaches that by using the Ig construct the Ig-peptide construct was 1000 times more effective in activating T cells than peptide alone because the Ig-peptide construct allowed for peptides to be endocytosed and processed internally which significantly increased the ability of the peptide to be bound by the MHC class II molecule while free synthetic peptides have to bind the low number of free MHC class II molecules at the cell surface to have their effect (page 26, column 2, 2nd paragraph). So increased T cell prevention activity in vitro by the Ig-peptide construct over the free peptide was expected, not unexpected. As far as Applicant's contention that the data shown in the 1.132 declaration demonstrates the prevention of T cell activation, this statement is not supported by the art, Kuchroo et al. The Declarant did not test T cell activation in the in vivo study with the Ig-PLP antagonist construct. Kuchroo et al., did test with peptide alone and found that even though the disease was inhibited, the animals T cell proliferative response to the original immunizing antigen, PLP 139-151, was increased over control animals who had the disease (see Table IV, in particular). Since the state of the art teaches away from Applicant's unexpected result in vivo and Applicant has no data to support said unexpected result in vivo, there is no recognized unexpected result.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period,

then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Tuesday through Friday from 8:30 am to 4:30 pm.

5. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7939. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Patrick J. Nolan, Ph.D.
Primary Examiner, Group 1640
December 30, 2001